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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,683	04/21/2000	Lawrence Xavier Webb, M.D.	F. 003	6497

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/553,683	<b>Applicant(s)</b> WEBB, M.D., LAWRENCE XAVIER	
	<b>Examiner</b> Eleni Mantis Mercader	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-30, 32, 34-57, 59 and 61-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 and 29 is/are allowed.
- 6) ☒ Claim(s) 30, 32, 34-57, 59 and 61-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Arguments***

Applicant's arguments filed on 12/21/2004 have been fully considered but they are not persuasive. Applicant argues that there is criticality because of the potential advantage of unique labels as facilitating surgery (citing specification p.19, lines 11-29). The Examiner respectfully disagrees as previously stated that because in the same paragraph, in last sentence, it is stated that if the squares are too small then the unique identifiers can be placed in the margins, thereby clearly indicating the Examiner's argument of lack of criticality and alternative functional equivalency. With respect to the cutout, in the broadest reasonable interpretation the Examiner's position is that when a biopsy needle enters the surgical drape there is necessarily a cutout. Finally the addition of the sterile limitation is inherent in any medical procedure in order to avoid contamination of the surgical field. For all of these reasons the rejections are maintained and made final.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 30, 32, 34-38, 41-43, 47-49, 53-61, 67 and 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller'762, of record in view of Krupnick'035, also of record.

Muller'762 teach all the features of the instant invention including a drape with radio-opaque grid lines 53 which are vertical and horizontal (see col. 6, lines 18-36) which are

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uniquely identifiable by letters and numbers as indicated by Figure 1. Adhesive is provided on a major portion of the drape (see col. 5, lines 15-18). Muller'762 does not teach the use of imaging technology wherein a pattern is obtained corresponding to the radio-opaque labels on the surgical drape.

In the same field of endeavor, Krupnick'035 teaches the use of imaging technology wherein a pattern is obtained corresponding to the radio-opaque labels on the surgical drape (see Figure 4 and see col. 5, lines 5-16). Krupnick'035 also teaches a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller'762 to incorporate the teachings of Krupnick'035 in order to utilize imaging to more correctly identify the area for biopsy (motivation to combine provided by Krupnick'035 in col. 5, lines 15-16, reciting that imaging technology through the radio-opaque flexible substrate expedites localization of the area of interest).

3. Claims 39-40, 44-46, 50-52 and 62-57, 59, 61-66, 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller'762 in view of Krupnick'035 and Mosby'985, all of record.

Muller'762 in view of Krupnick'035 teach all the features of the instant invention as set forth in paragraph 3 above, except for the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger.

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Mosby'985 teaches the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger (see col. 5, lines 7-12; col. 6, lines 38-47 and col. 7, lines 1-10).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller'762 in view of Krupnick'035 to incorporate the teaching of Mosby'985 when using the drape during biopsy procedures of areas such as the breast or the finger to more readily localize the area of interest for biopsy using circular radio-opaque indications.

*Allowable Subject Matter*


4. Claims 28 and 29 are allowed.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM